

Designation Run Report

Harper-Avilla, Stacy - Plaintiffs' Submission

Harper-Avilla, Stacy 04-11-2019

Plaintiffs Affirmative Designations 00:15:26

Plaintiff Counter Counters 00:00:13

Defense Completeness Counters 00:01:14

Total Time 00:16:52



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16:17 - 16:19	Harper-Avilla, Stacy 04-11-2019 (00:00:05) 16:17 Would you just state your full name 16:18 for the record. 16:19 A. Stacy Harper-Avilla.	SH03.81
17:22 - 18:01	Harper-Avilla, Stacy 04-11-2019 (00:00:09) 17:22 Q. And you understand that today you 17:23 are providing testimony on behalf of the DEA? 17:24 A. Yes. 17:25 MR. O'CONNOR: I'm going to mark 18:1 Exhibit 1.	SH03.1 P-41927_1.1
18:02 - 18:11	Harper-Avilla, Stacy 04-11-2019 (00:00:27) 18:2 (Deposition Exhibit 1 was marked for 18:3 identification.) 18:4 BY MR. O'CONNOR: 18:5 Q. This is a notice of deposition. 18:6 Have you ever seen this document 18:7 before? 18:8 A. Yes. 18:9 Q. And I'm going to ask you to turn to 18:10 Exhibit B, which is the letter from the U.S. 18:11 Department of Justice.	SH03.2 P-41927_1.13.1 - P-41927_1.14
18:12 - 18:20	Harper-Avilla, Stacy 04-11-2019 (00:00:29) 18:12 Have you ever seen this document 18:13 before? 18:14 A. Yes. 18:15 Q. Okay. And do you understand it to 18:16 be the letter authorizing testimony on certain 18:17 subjects on behalf of the DEA? 18:18 A. Yes. 18:19 Q. Let's go ahead and turn to Page 6 18:20 and I direct your attention to Topic 13.	SH03.3 P-41927_1.14.1 P-41927_1.19.1 P-41927_1.19.2
18:21 - 19:09	Harper-Avilla, Stacy 04-11-2019 (00:00:44) 18:21 It says: "Topic 13. Your practices 18:22 and procedures related to the establishment of 18:23 opioid procurement quotas and opioid production 18:24 quotas for prescription opioids." 18:25 Are you authorized by the DEA to 19:1 testify regarding that topic today? 19:2 A. Yes. 19:3 Q. And I now direct your attention to:	SH03.4 P-41927_1.19.4

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clear

21:18 Q. Ms. Avilla, what is your current

21:19 role at DEA?

21:20 A. I'm the section chief of United

21:21 Nations Reporting and Quota Section.

21:22 Q. And what do your responsibilities in

21:23 that role include?

21:24 A. The responsibilities are to manage

21:25 the quotas for controlled substances in

22:1 Schedules I and II, report back to the UN on

22:2 the U.S. -- usage consumption of those

22:3 substances as well as for setting the

22:4 assessments and estimates for items in

22:5 Schedules III through V, controlled substances

22:6 in III through V.

22:7 Q. How long have you been in that

22:8 position?

22:9 A. Since July of last year.

22:10 Q. Before that, did you hold any

22:11 position at DEA?

22:12 A. Yes, I did.

22:13 Q. What was that?

22:14 A. I was the unit chief of the same

22:15 section.

22:16 Q. You were working with quotas in that

22:17 role as well?

22:18 A. Yes.

22:19 Q. What was your position at DEA, if

22:20 any, before that time?

22:21 A. I don't understand the question.

22:22 Q. Did you have a job at DEA before

22:23 that role as unit chief?

22:24 A. Yes.

22:25 Q. What was that?

23:1 A. Drug science specialist.

23:2 Q. Okay. When you were a drug science

23:3 specialist, did you have any involvement in

23:4 quota issues?

23:5 A. Yes.

23:6 Q. Was that role your first at DEA?

23:7 A. Yes.

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23:8	Q. And when did you start in that role?	
23:9	A. 2008.	
23:10 - 23:16	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.8
23:10	Q. So am I correct that you joined the	
23:11	Drug Enforcement Administration in 2008?	
23:12	A. Correct.	
23:13	Q. Okay. And since that time, your	
23:14	work has included work on quota-related	
23:15	matters?	
23:16	A. Yes.	
49:02 - 49:04	Harper-Avilla, Stacy 04-11-2019 (00:00:07)	SH03.13
49:2	Q. Okay.	
49:3	MR. O'CONNOR: I'm going to mark	
49:4	Exhibit 2.	P-41928_1.1
49:05 - 49:14	Harper-Avilla, Stacy 04-11-2019 (00:00:24)	SH03.14
49:5	(Deposition Exhibit 2 was marked for	
49:6	identification.)	
49:7	BY MR. O'CONNOR:	
49:8	Q. Do you recognize this document?	P-41928_1.1.1
49:9	A. Yes.	
49:10	Q. What is it?	
49:11	A. It is a page from the C.F.R.	
49:12	Q. Okay. Was this a portion of the	
49:13	C.F.R. that you used in connection with your	
49:14	role as unit chief and section chief?	
49:17 - 49:22	Harper-Avilla, Stacy 04-11-2019 (00:00:14)	SH03.15
49:17	THE WITNESS: I don't understand the	
49:18	question.	
49:19	BY MR. O'CONNOR:	
49:20	Q. Okay. When you were working on	
49:21	quota issues, did you ever refer to this	
49:22	regulation?	
49:24 - 50:24	Harper-Avilla, Stacy 04-11-2019 (00:01:24)	SH03.16
49:24	THE WITNESS: Can I have the	
49:25	question back.	
50:1	BY MR. O'CONNOR:	
50:2	Q. Sure. When you were working on	
50:3	quota issues, did you ever refer to this	
50:4	regulation?	
50:5	A. When I was working on the aggregate	

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	50:6 production quota, then this section that you	
	50:7 printed, yes.	
	50:8 Q. And specifically, I would like to	
	50:9 talk about Section 1303.11(b), which says: "In	P-41928_1.1.2
	50:10 making this determination, the administrator	
	50:11 shall consider the following factors."	
	50:12 Do you see that?	
	50:13 A. Yes.	
	50:14 Q. Okay. And then it goes on to list	
	50:15 five items.	
	50:16 The first is: "Total net disposal	P-41928_1.1.3
	50:17 of the class by all manufacturers during the	
	50:18 current and two preceding years."	
	50:19 Did DEA consider that factor when	
	50:20 setting the aggregate production quotas between	
	50:21 1995 and 2018?	
	50:22 A. Yes.	
	50:23 Q. And what does it mean to say the	
	50:24 "total net disposal of the class?"	P-41928_1.1.4
50:25 - 51:12	Harper-Avilla, Stacy 04-11-2019 (00:01:00)	SH03.17
	50:25 A. So total net disposal would be the	
	51:1 aggregate disposal disposition of all the	
	51:2 manufacturers, not counting their manufacturing	
	51:3 losses or their returns to other manufacturers.	
	51:4 Q. Okay. Okay. No. 2 says: "Trends	P-41928_1.1.5
	51:5 in the national rate of net disposal of the	
	51:6 class."	
	51:7 What does that mean?	
	51:8 A. Trends in national rate would be	
	51:9 changes in disposal rates.	
	51:10 Q. How would DEA take into account	
	51:11 trends in the national rate of net disposal	
	51:12 when determining aggregate production quotas?	
51:13 - 52:24	Harper-Avilla, Stacy 04-11-2019 (00:02:21)	SH03.18
	51:13 A. The main factor would be from FDA.	
	51:14 Q. Okay. And in each year from 1995 to	
	51:15 2018, did DEA, in fact, consider the trends in	
	51:16 the national rate of net disposal of the class	
	51:17 when setting aggregate production quotas?	
	51:18 A. Yes.	

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	53:9 THE WITNESS: It would be the number 53:10 of manufacturers, their actual use and need for 53:11 the material, known diversion, known abuse. 53:12 BY MR. O'CONNOR: 53:13 Q. And were those factors you just 53:14 listed considered every year between 1995 and 53:15 2018?	
53:17 - 53:18	Harper-Avilla, Stacy 04-11-2019 (00:00:02) 53:17 THE WITNESS: When there was data, 53:18 yes.	SH03.22
116:11 - 116:15	Harper-Avilla, Stacy 04-11-2019 (00:00:19) 116:11 Q. But it's true that DEA understands 116:12 that ultimately, pharmacies may dispense to 116:13 patients across this country, an amount of the 116:14 controlled substance that is set by the 116:15 aggregate production quota, correct?	SH03.55 clear
116:18 - 116:20	Harper-Avilla, Stacy 04-11-2019 (00:00:06) 116:18 THE WITNESS: A pharmacy may 116:19 dispense an amount needed for legitimate 116:20 patient need.	SH03.56
118:18 - 118:21	Harper-Avilla, Stacy 04-11-2019 (00:00:13) 118:18 Q. Well, in setting the annual 118:19 production quota, would you agree that DEA has 118:20 the ability to control how much of a 118:21 prescription opioid is available to the public?	SH03.57
118:24 - 119:08	Harper-Avilla, Stacy 04-11-2019 (00:00:22) 118:24 THE WITNESS: I would not. 118:25 BY MR. EPPICH: 119:1 Q. Why not? 119:2 A. Because there are many other factors 119:3 in between the number that is set and what goes 119:4 out to the public. 119:5 Q. What are those factors? 119:6 A. Manufacturing losses and yield, FDA 119:7 recalls, FDA changes in market practices, 119:8 manufacturers losing contracts, among others.	SH03.58
139:15 - 139:20	Harper-Avilla, Stacy 04-11-2019 (00:00:18) 139:15 Q. Is the responsibility for 139:16 manufacturers and distributors to monitor for 139:17 suspicious orders, stopping shipments of	SH03.59

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139:25 - 140:11	<p>139:18 suspicious orders and inform the DEA, does that 139:19 responsibility go away because there is a quota 139:20 system in place by the DEA?</p> <p>Harper-Avilla, Stacy 04-11-2019 (00:00:26)</p> <p>139:25 THE WITNESS: So the quota system is 140:1 one portion of it, but it's incumbent upon the 140:2 manufacturers and distributors and all of the 140:3 participants within the quota system, within 140:4 the controlled substance system, to do their 140:5 part as per the regulations. 140:6 BY MR. ELSNER: 140:7 Q. Okay. So simply because there is a 140:8 quota system in place, that doesn't excuse 140:9 manufacturers and distributors from fulfilling 140:10 their other obligations under the Controlled 140:11 Substances Act; is that right?</p>	SH03.60
140:14 - 140:14	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:01)</p> <p>140:14 THE WITNESS: True.</p>	SH03.61
151:01 - 151:03	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:07)</p> <p>151:1 Q. Okay. The quota system run by the 151:2 DEA is also national in scope; is that right? 151:3 A. Correct.</p>	SH03.82
151:04 - 151:09	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:14)</p> <p>151:4 Q. Okay. It didn't -- it doesn't look 151:5 at -- the quota system for the DEA doesn't look 151:6 at how many pills a distributor like 151:7 AmerisourceBergen or Cardinal could distribute 151:8 to a particular pharmacy in a particular 151:9 community, does it?</p>	SH03.62
151:12 - 151:12	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:02)</p> <p>151:12 THE WITNESS: It does not.</p>	SH03.63
151:14 - 151:19	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:17)</p> <p>151:14 Q. Okay. And the quota system, even if 151:15 you reduce the quota, it couldn't prevent a 151:16 distributor like McKesson from distributing 151:17 112,000 doses units of Hydrocodone products 151:18 into one pharmacy in West Virginia with a 151:19 population of 1500 people, could it?</p>	SH03.64
151:23 - 151:25	<p>Harper-Avilla, Stacy 04-11-2019 (00:00:06)</p> <p>151:23 THE WITNESS: The quota system is</p>	SH03.65

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151:24 national so it has no control over distributor 151:25 contracts.		
152:02 - 152:11	Harper-Avilla, Stacy 04-11-2019 (00:00:19)	SH03.66
152:2 Q. And the DEA, through the quota 152:3 system, it doesn't analyze and approve 152:4 individual orders from pharmacies, to 152:5 manufacturers or to wholesale distributors, 152:6 does it? 152:7 A. It does not. 152:8 Q. Okay. And the quota system doesn't 152:9 authorize the number of pills that could be 152:10 distributed into Summit County or Cabell County 152:11 in West Virginia, does it?		
152:14 - 152:20	Harper-Avilla, Stacy 04-11-2019 (00:00:16)	SH03.67
152:14 THE WITNESS: It does not. 152:15 BY MR. ELSNER: 152:16 Q. And it doesn't authorize the number 152:17 of pills that a distributor could send to any 152:18 city or county in the United States, does it? 152:19 A. It does not. It is national. It is 152:20 not county, not city, not state-specific.		
177:03 - 177:07	Harper-Avilla, Stacy 04-11-2019 (00:00:12)	SH03.68
177:3 Q. Ma'am, as you pointed out, the DEA 177:4 didn't just rely on the manufacturer's 177:5 information to set quota. The DEA also looked 177:6 at prescription data; is that true? 177:7 A. Correct.		
177:09 - 177:20	Harper-Avilla, Stacy 04-11-2019 (00:00:43)	SH03.69
177:9 BY MR. ELSNER: 177:10 Q. And did that include data provided 177:11 by IMS and later equivalence of that company? 177:12 A. Yes. 177:13 Q. And would you agree with me that if 177:14 manufacturers and distributors of opioids had 177:15 misled doctors and the public about the health 177:16 benefits and the addictive nature of opioids 177:17 they were manufacturing and distributing 177:18 causing sales to rise, then the DEA's estimate 177:19 of the medical need could be above the actual 177:20 medical need in the United States?		

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177:25 - 177:25	Harper-Avilla, Stacy 04-11-2019 (00:00:01) 177:25 THE WITNESS: Yes.	SH03.70
186:05 - 186:09	Harper-Avilla, Stacy 04-11-2019 (00:00:12) 186:5 Q. Okay. Now if the supply was limited 186:6 -- so I am done with the document now. 186:7 If the supply were limited, if you 186:8 decreased the quota, would that stop all 186:9 diversion?	SH03.71
186:11 - 186:11	Harper-Avilla, Stacy 04-11-2019 (00:00:01) 186:11 THE WITNESS: No.	SH03.72
186:20 - 186:21	Harper-Avilla, Stacy 04-11-2019 (00:00:07) 186:20 Q. It would simply mean that gross bulk 186:21 amount of a particular gross drug type would be	SH03.73
186:22 - 186:22	Harper-Avilla, Stacy 04-11-2019 (00:00:01) 186:22 less, correct?	SH03.74
186:25 - 186:25	Harper-Avilla, Stacy 04-11-2019 (00:00:01) 186:25 THE WITNESS: Correct.	SH03.75
187:20 - 187:23	Harper-Avilla, Stacy 04-11-2019 (00:00:14) 187:20 Q. And so if we reduce the size of the 187:21 quota simply reduces the pool of available 187:22 drugs, both to the licit and illicit users of 187:23 that drug, correct?	SH03.76
188:03 - 188:07	Harper-Avilla, Stacy 04-11-2019 (00:00:07) 188:3 THE WITNESS: It reduces the amount 188:4 of material available, period. 188:5 BY MR. ELSNER: 188:6 Q. Across the board? 188:7 A. Across the board.	SH03.77
218:02 - 218:09	Harper-Avilla, Stacy 04-11-2019 (00:00:15) 218:2 Q. Earlier in the deposition, you were 218:3 asked a question that -- during the years that 218:4 you approved the quota numbers, did you feel 218:5 that they reflected the medical need of the 218:6 United States? 218:7 Do you remember that line of 218:8 questioning? 218:9 A. Yes.	SH03.78
218:14 - 218:17	Harper-Avilla, Stacy 04-11-2019 (00:00:14) 218:14 Q. And you answered that you believed 218:15 that when you were approving quota allocations,	SH03.79

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218:21 - 218:24	<p>218:16 they were based on legitimate medical need.</p> <p>218:17 Do you remember that testimony?</p> <p>Harper-Avilla, Stacy 04-11-2019 (00:00:09)</p> <p>218:21 THE WITNESS: So when I approved</p> <p>218:22 quota, it was for a legitimate medical need or</p> <p>218:23 scientific or research purposes or export or</p> <p>218:24 inventory.</p>	SH03.80
<p>Plaintiffs Affirmative Designations = 00:15:26</p> <p>Plaintiff Counter Counters = 00:00:13</p> <p>Defense Completeness Counters = 00:01:14</p> <p>Total Time = 00:16:52</p> <p>Documents Shown</p> <p>P-41927_1</p> <p>P-41928_1</p>		